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Penumbra

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(c)

510(k) Number	K053491
Date Summary Prepared	April 20, 2006
Trade Name	Penumbra Balloon Guide Catheter
Common Name	Balloon Guide Catheter
Classification Name	Percutaneous Catheter, Balloon Type Catheter (21 CFR Part 870.1250, 21CFR 878.4200; Product Code DQY)
Submitted By	Penumbra, Inc. 2401 Merced Street, Suite 200 San Leandro, CA 94577
Contact	Theresa Brander-Allen VP of Regulatory and Quality Tel: 510-618-3223 Fax: 510-352-1766 tballen@penumbrainc.com

Predicate Device
Concentric Balloon Guide Catheter (K021899)
Manufactured by Concentric Medical, Inc.

Device Description
The Penumbra Balloon Guide Catheter is a coaxial-lumen, braid-reinforced, variable stiffness catheter with a radiopaque markerband on the distal end and bifurcated Luer hub on the proximal end. A semi-compliant balloon is flush mounted on the distal end. During use, the balloon may be inflated to temporarily occlude blood flow, and the catheter lumen may be used to provide a conduit for passage of vascular devices. The design combines the features of a guide catheter with the features of a semi-compliant balloon catheter.

Materials used in the Penumbra Balloon Guide Catheter are manufactured from medical grade materials that are commonly used in the industry, are similar or identical to the predicate device, and have historically been demonstrated to be both biocompatible and suitable for this use.

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Intended Use

The Penumbra Balloon Guide Cathcter is indicated for temporary occlusion of blood flow and to serve as a conduit for devices used in the neurovasculature. The indication statement of the Penumbra Balloon Guide Catheter is substantially equivalent to the legally marketed predicate device.

Substantial Equivalence

The intended use, method of operation, methods of construction and materials used, are either identical or substantially equivalent to the existing, legally marketed, predicate device. Therefore, Penumbra believes the Penumbra Balloon Guide Catheter is substantially equivalent to the predicate device.

Testing

Bench testing, *in vitro* testing, and *in vivo* testing have been performed on the device materials, components, subassemblies, and final assemblies. The devices tested acceptably met the specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 27 2006

Penumbra, Inc.
c/o Ms. Theresa Brandner-Allen
VP of Regulatory and Quality
2401 Merced Street – Suite 200
San Leandro, California 94577

Re: K053491
Trade/Device Name: Penumbra Balloon Guide Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: II
Product Code: DQY
Dated: March 29, 2006
Received: March 30, 2006

Dear Ms. Brandner-Allen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K053491

Device Name: Penumbra Balloon Guide Catheter

Indications for Use: The Penumbra Balloon Guide Catheter is indicated for temporary occlusion of blood flow and to serve as a conduit for devices used in the neurovasculature.

Prescription Use _X_ (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use____ (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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